STATEMENT OF CLAIMS STATUS

Claims 1-24 are pending.

Claims 1-24 are rejected .

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SUMMARY OF RESPONSE

Claim Rejections - 35 USC § 112

1. Examiner States: "Claims 1-13, 16, 18-20 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

2. Examiner States: "Claim 1 is unclear as there are no method steps positively recited therein. In claim 6 it is unclear what further limitation is intended to be recited given that claim 1 already requires the absence of blood. Claim 16 is indefinite as it unclear what further structure is to be implied by reciting the effect of the anesthesia on the tissue and " the anesthesia" lacks positive antecedent basis. Claim 18 is indefinite as it is unclear what structure not inherent in a catheter is intended to be inferred. Claim 24 is incomplete as there is not enough structure in the fiber itself to perform the function of thermal sensing."

Claim Rejections - 35 USC § 103

3. Examiner States: "Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al. Goldman et al ('084) teaches a method as claimed, but does not specif~r a wavelength. Dew et al teach the desirability of using 1.3 micron radiation to treat tissue. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, thus producing a method such as claimed."

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4. Examiner States: "Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al as applied to claims 1, 2, 6, and 7 above, and further in view of Roth et al. Roth et al teach employing pull back rate as claimed, noting that the desired rate is dependent on the laser energy. It would have been obvious to the artisan of ordinary skill to employ a pull back rate as claimed, since there are known in the art and provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art official notice of which is hereby taken, thus producing a method such as claimed."

5. Examiner States: "Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al as applied to claims 1, 2, 6, and 7 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed, it would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue, thus producing a method such as claimed."

6. Examiner States: "Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al as applied to claims 1, 2, 6 and 7 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using infrared sensing techniques. It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed."

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7. Examiner States: "Claims 14-18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the laser wavelength of Dew et al in the device of Makower et al, since Makower et al teach the use of an Nd: YAG laser and to employ the pull back mechanism of Roth et al, since this enables uniform treatment along a lumenal surface, as taught by Roth et al, thus producing a device such as claimed."

8. Examiner States: "Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et a! and Roth as applied to claims 14-18 and 20-24 above, and further in view of Conn et ai. Conn et al teach a diffusing tip as part of an introducer device for a fiber. It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et a!, thus producing a device such as claimed."

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CLAIMS AMENDMENTS

1. (currently amended) An endovenous method of treating ~~a~~ varicose veins comprising the step of using a laser having a wavelength between about 1.2 and about 1.8 um to heat and shrink collagen in a varicosed ~~vessel wall in the absence of blood~~ vein and to destroy the endothelial cells within the varicose vein.

2. (original) The method of Claim 1 in which the laser energy is delivered with a fiber optic laser delivery device.

3. (original) The method of Claim 1 further comprising the following steps:

Inserting a fiber optic laser delivery device into the varicose vein;

Using a pullback device to retract the fiber optic laser delivery device through the varicose vein at a rate of between about 0.1 mm/sec and about 10.0 mm/sec while simultaneously delivering laser energy therefrom.

4. (original) The method of Claim 3 in which the fiber optic laser delivery device is retracted at a rate of between about 1.0 mm/sec and about 5.0 mm/sec.

5. (original) The method of Claim 3 in which the pullback device begins retraction of the fiber optic laser delivery device just prior to initiating delivery of the laser energy, thereby preventing the tip of the fiber optic laser delivery device from sticking to the vessel wall.

6. (currently amended) The method of Claim 1 ~~in which blood is removed~~ further comprising the preliminary step of removing blood from the varicosed vein prior to treatment with laser energy.

7. (original) The method of Claim 2 in which the fiber optic laser delivery device is introduced to the varicose vein through an introducer catheter.

8. (original) The method of Claim 2 in which the energy delivered through the fiber optic laser delivery device is evenly distributed by using a diffuse radiating tip mounted to the distal end of the fiber optic laser delivery device.

9. (original) The method of Claim 2 in which an non-contact thermal sensor is used to maintain a desired temperature.

10. (original) The method of Claim 9 in which the thermal sensor is used to maintain a desired coagulation temperature.

11. (original) The method of Claim 9 in which the thermal sensor is used to maintain a desired collagen shrinkage temperature.

12. (currently amended) The method of Claim 9 further comprising the step of using the fiber optic laser delivery device as a thermal sensing element.

13. (original) The method of Claim 9 further comprising the step of modulating the laser power based on the sensed temperature to maintain the desired temperature.

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14. (currently amended) A system for endovenous treatment of varicose veins comprising the following:

A laser having a wavelength between about 1.2 and about 1.8 um; and

A fiber optic laser delivery device having a proximal end and a distal end, for delivery of laser energy from the distal end of the fiber optic laser delivery device to the inside wall of a varicose vein; ~~and~~

~~A pullback device which retracts the fiber optic laser delivery device through the varicose vein at a rate of between about 0.1 mm/sec and about 10.0 mm/sec while simultaneously delivering laser energy therefrom, wherein collagen in the varicosed vessel wall can be heated and shrunk in the absence of blood~~ wherein the endothelial cells are destroyed and collagen in the varicosed vessel wall can be heated and shrunk.

15. (currently amended) The system of Claim 14 ~~in which the~~ further comprising a pullback device which retracts the fiber optic laser delivery device through the varicose vein at a rate of between about ~~1.0~~ 0.1 mm/sec and about ~~5.0~~ 10.0 mm/sec.

16. (currently amended) The system of Claim 14 further comprising ~~anesthesia administered~~ means for administration of anesthesia to tissue surrounding the varicose vein, wherein the anesthesia causes swelling of the tissue surrounding the varicose vein which causes compression of the varicose vein in order to remove blood prior to treatment.

17. (currently amended) The system of Claim 14 further comprising an introducer catheter in which an elongated lumen portion has a proximal end and a distal end, wherein the fiber optic laser delivery device is introduced to the introducer catheter through the proximal end and is introduced to the varicose vein through the distal end. wherein, ~~wherein the fiber optic laser delivery device can be introduced to the varicose vein~~.

18. (canceled)

19. (original) The system of Claim 18 further comprising a diffusing tip at the distal end of the introducer catheter for providing even distribution of energy radiating during treatment.

20. (original) The system of Claim 18 further comprising a diffusing tip at the distal end of the fiber optic laser delivery device for providing even distribution of energy radiating during treatment.

21. (original) The system of Claim 14 further comprising an non-contact thermal sensor.

22. (original) The system of Claim 21 further comprising a controller coupled to the thermal sensor for controlling the temperature in a region near the distal end of the fiber optic laser delivery device.

23. (original) The system of Claim 22 in which the controller modulates a power input to the laser for controlling the temperature in a region near the distal end of the fiber optic laser delivery device.

24. (canceled)

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25. (new) An endovenous method of treating varicose veins with laser energy to heat and shrink collagen in the vein and to destroy the endothelial cells within the varicosed vein, the method comprising the following steps:

Inserting a laser delivery device into the varicose vein;

Delivering laser energy having a wavelength between about 1.2 and about 1.8 um to the varicose vein; and

Retracting the laser delivery device through the varicose vein, thereby heating and shrinking the collagen in the vein and destroying the endothelial cells in the varicose vein.

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REMARKS

Remark 1:

With all due respect, in response to the Examiner's rejection Applicant has amended Claim 1 to more positively recite the inventive step(s). Applicant respectfully submits that the amendments to Claim 1 overcome the rejections of the claim.

Remark 2:

With all due respect, in response to the Examiner's rejection Applicant has amended Claim 16 to more positively recite the novel structure. Applicant respectfully submits that the amendments to Claim 16 overcome the rejections of the claim.

Remark 3:

With all due respect, in response to the Examiner's rejection Applicant has amended Claim 17 and more positively recite the structural limitations of original Claim 18. Applicant has further canceled original Claim 18. Applicant respectfully submits that the amendments overcome the rejections of Claim 18.

Remark 4:

With all due respect, in response to the Examiner's rejection Applicant has amended Claim 12 to recite the functional limitations of structure claimed in original Claim 24. Applicant has further canceled Claim 24. Applicant respectfully submits that the amendments overcome the rejections of Claim 24.

Remark 5:

With all due respect, Applicant requests the Examiner withdraw Goldman et al as an anticipating reference under 35 USC 103(a). Goldman et al fails to teach of an endovenous method of treating a

varicose vein comprising the step of using a laser having a wavelength between about 1.2 and about 1.8 um for heating and shrinking collagen and destroying endothelial cells in a varicosed vessel wall.

Goldman is directed to a method of ligation, i.e., heating and occluding veins using RF energy. Goldman does not teach the use of a laser having an output in the range of about 1.2 to about 1.8 um. Goldman does not teach heating and shrinking collagen in a varicosed vessel wall to destroy endothelial cells. Nor does Goldman teach the use of a retraction device or pull-back device as described in the present invention.

However, the present invention is based on the strong absorption of the emitted energy having the recited wavelength range **in water**. In contrast with the prior art which relies upon the absorption of energy by hemoglobin, since the longer wavelength energy is selectively absorbed by the water in the tissue, localized necrosis and destruction of the undesirable varicose vein is possible with the present invention. In Goldman, using RF energy to cause ablation and necrosis is neither anticipated nor is it possible. In Goldman, the anticipated result is ligation. In the present invention, however, the result is necrosis, i.e., a total destruction of the varicose vein.

Remark 6:

With all due respect, Applicant hereby submits the following list of distinctions between the teachings of Goldman et al and the present invention:

(a) Goldman et al requires a catheter with an energy application device on the working end. However, the present invention does not have this requirement. In a preferred embodiment, the working end of the present invention is a fiber optic is bare fiber. There is no separate device at the distal, laser energy delivery end. The fiber is the same the entire length of the catheter and simply terminates at the working end.

(b) Goldman et al requires that the working end of the catheter be positioned proximate a treatment site. The present invention does not require the working end to be proximate the treatment site. In fact the present invention does not work proximate to the treatment site because in the preferred method of the present invention, a bare fiber is used which directs the laser energy out of the end of the fiber so that the treatment site is several mm in front of the working end, not proximal or to the side of the fiber.

(c) Goldman et al requires tumescent anesthesia to compress the vein. The present invention, however, will work effectively in the absence of tumescent anesthesia, but the use of tumescent anesthesia reduces pain and swelling.

(d) Goldman et al states that the object of their treatment is to apply energy "until the hollow structure...assumes a smaller size". The object of the present invention, however, is different. The present invention works by heating the endothelial cells of the vein until they are totally necrosed. In most cases this also results in some shrinkage of the vein, but shrinkage is not the most important endpoint. A vein can be shrunk in size but if the endothelial cells are still viable the vein may regenerate. The 1.2 to 1.8 um laser energy used in the present invention works by selectively heating the endothelial cells.

Remark 7:

With all due respect, Applicant requests the Examiner withdraw Dew et al as an anticipating reference under 35 USC 103(a). Dew et al teaches a method and apparatus for tissue welding and wound closure and the use of a laser having a wavelength of 1.32 um. However, Dew et al does not suggest that such laser energy may be directed through a fiber optic laser energy delivery device, nor does Dew et al suggest the treatment of varicose veins close to the surface of the skin in the lower trunk or legs.

Remark 8:

Applicant respectfully points out, the following distinctions with Dew et al and the present invention:

(a) Dew et al only suggests the use of laser energy for heating tissue to the point it becomes "sticky" and grow back through the process of reconstruction. In direct contrast, the present invention teaches necrosis to the point of destruction, such that upon reabsorption of the necrosed tissue the veins are literally destroyed.

(b) Dew et al teaches careful control of the temperature and time of treatment to avoid tissue necrosis. In contrast, overtreatment in the present invention is of little consequence, other than perhaps slight discomfort in the case of gross overtreatment. Nevertheless, overtreatment in the present invention still leads to vein necrosis and is therefore not undesirable for that reason.

(c) An objective of Dew et al is to preserve tissue. The present invention, however, relies upon destruction of tissue.

(d) Combining Goldman et al and Dew et al would, therefore, never result in a treatment wherein the varicose veins themselves are destroyed. The veins would perhaps temporarily occlude, but then would reconstruct as taught in Goldman et al and Dew et al.

(e) Dew et al utilizes a thermal feed back device that will hold the tissue at a precise temperature for a precise amount of time. The present invention utilizes a fairly insensitive thermal feedback system to ensure that the tissue is heated at least up to or beyond the necrosis point, but still less than the point that will cause pain. In the present invention, there is no upper threshold of amount of energy that can be delivered to the vein and still be effective. At a typical power of 5 watts, it is possible to activate the laser without the use of the pullback device, and let the laser energy necrose the tissue without any undesired effects to the point of destruction of the vein. Such unlimited treatment in